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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/553,546 | 09/12/2006 | Patrick Hanley | PA1365 | 4055 |

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

| EXAMINER | |
|---|---|
| PEZZUTO, HELEN LEE | |
| ART UNIT | PAPER NUMBER |
| 1796 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/15/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/553,546 | HANLEY ET AL. | |
| | Examiner | Art Unit | |
| | Helen L. Pezzuto | 1796 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-19,21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19,21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

***Response to Amendment***

Applicant's amendment to claims 15 and the cancellation of claims 20, 22, and 26-28 filed in the response on 5/12/09 is acknowledged. Currently, claims 15-19, 21, and 23-25 are pending in this application.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 15-19, 21, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garnett et al. (US-511) for the reasons of record.

US 6,162,511 to Garnett et al. discloses a radiation curable coating composition comprising a resin component including an unsaturated monomer, and an unsaturated oligomer/prepolymer, and binder or mixture thereof (see abstract). Suitable substrate material includes plastics such as polyolefins and metals, which fall within the scope

of the instant biomedical device (col. 7, lines 63-67). Specifically, suitable unsaturated monomers include unsaturated carboxylic acid (e.g. acrylic acid), N-vinylpyrrolidone, and multifunctional acrylate within the scope of claim 2 (col. 2, lines 34-54). Prior art oligomer or prepolymer such as unsaturated polyethers and acrylate oligomers, clearly fall within the scope of the instant relatively lower molecular weight polymer (col. 2, line 55 to col. 3, line 4). Suitable higher molecular weight binder polymer includes polyvinylpyrrolidone, encompassing the instant higher molecular weight polymer expressed in claim 14 (col. 3, lines 4-16). Prior art discloses molecular weight of the prepolymer and binder polymer ranges from 2,000 to 200,000, encompass those expressed in claim 21. Hydrogen abstracting photoinitiator such as benzophenone and reaction solvent were also taught (col. 3, lines 38-39; col. 4, lines 22-24). Accordingly, one having ordinary skill in the art would have readily envisage selecting the claimed components in the preparation of a coating composition suitable for coating on an implantable biomedical device, motivated by the reasonable expectation of success. Once the motivation to select the suitable components is provided, it would have been obvious to one

having ordinary skill in the art to determine the optimum or workable ranges of each component, and their relative proportions via routine experimentation.

3. Claims 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/48202 A1 for the reasons of record.

WO-202 discloses a process for producing scratch-resistant coatings comprising a photocurable formulation. Specifically, prior art process comprises preparing a photocurable formulation comprising at least one ethylenically unsaturated compound (A), a photoinitiator of formula Ia or Ib, applying the formulation to an substrate and curing the formulation by either solely irradiation with electromagnetic radiation and/or action of heat (see abstract, pages 1-2, 16). Suitable ethylenically unsaturated component (A) can be monomeric, oligomeric and polymeric, encompassing the instant hydrophilic monomer, and the high and low molecular weight polymers (pages 16-17, 22). WO-202 specifically teaches that the photopolymerizable compounds (A) can be used alone or in any desired mixtures, wherein mixtures of polyol(meth)acrylates are preferably used (page 20, lines 19-20). Prior art further suggest adding polymeric binder having molecular weight ranges from 5,000 to 2,000,000, and

polyvinylpyrrolidone dispersant aids, defined within the scope of the instant high molecular weight polymer (pages 20-21). Suitable binder polymer includes polyethylene oxide and polycaprolactam (page 20, line 21 to page 21, line 10). Other conventional additives such as additional photoinitiators (i.e. benzophenones), and solvents are further disclosed (pages 30, 40, 42). Suitable coating substrates include polyolefins, and polyethylene terephthalate, within the scope of the instant medical device (page 38, lines 5-9). Prior art discloses a curing temperature ranges from room temperature to 150°C (page 44). Accordingly it would have been obvious to one having ordinary skill in the art to select a mixture of ethylenically unsaturated monomer, oligomer and high molecular weight polymer binders, a UV activable compound such as benzophenone, dispersant aids such as polyvinylpyrrolidone as needed, and an appropriate solvent to formulate a coating composition suitable for coating an implantable biomedical device as presently claimed, motivated by the reasonable expectation of success. Once the motivation to select the suitable components is provided, one having ordinary skill in the art would have

readily envisage the optimum or workable proportions of the respective components to the suitable application.

***Response to Arguments***

Applicant's amendment and remarks filed 5/12/09 have been fully considered. Firstly, applicant urges Garnett et al. provides a molecular weight range of 2,000-200,000 for both the prepolymer and higher molecular weight binder polymer, in contrast to those expressed in claim 21 which do not overlap. Applicant further urges that Garnett et al. do not provide guidance as to the ratios of prepolymer and binder polymer. The examiner is of the position that the recited molecular weights for both high and low molecular weight polymers are well within the range of 2,000-200,000 taught in prior art. Thus, a skilled artisan would recognize and select any prepolymer and binder polymer within the range taught by patentees, motivated by the reasonable expectation of success. Furthermore, it would have been obvious to one having ordinary skill in the art to discover the optimum prepolymer to binder polymer ratios suitable for specific considerations and applications, within prior art general conditions. For example, prior art teaches 50-1000 parts of urethane acrylate prepolymer based

on 100 parts by weight of the resin composition in a preferred embodiment (col. 4, lines 46-54), and further disclose suitable weight ratios of monomer to the prepolymer and binder polymer suitable for specific considerations and applications (col. 3, lines 17-25). Secondly, applicant urges that WO-202 does not specifically suggest a combination of both lower molecular weight and higher molecular weight polymers, and that unsaturated component (A) can serve three separate components. The examiner respectfully disagrees. WO-202 discloses at least one unsaturated component (A) which can be monomeric, oligomeric (i.e. prepolymers) and/or polymeric (page 15, line 26 to page 17, line 20). WO-202 specifically teaches that the photopolymerizable compounds (A) can be used alone or in any desired mixtures, wherein mixtures of polyol(meth)acrylates are preferably used (page 20, lines 19-20). Prior art further suggest adding polymeric binder having molecular weight ranges from 5,000 to 2,000,000, which further reads on the instant high molecular weight polymer. Thus, it would have been obvious to one having ordinary skill in the art to select a mixture of ethylenically unsaturated monomer, oligomer and high molecular weight polymer binders as taught within the scope

of the instant hydrophilic monomer, and high and low molecular weight polymers as taught. Accordingly, the examiner's position is maintained.

**4 THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen L. Pezzuto whose telephone number is (571) 272-1108. The examiner can normally be reached on 8 AM to 4 PM, Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached

on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Helen L. Pezzuto/
Primary Examiner
Art Unit 1796